

### § 118.3

(c) Within 48 hours after the detention of any biological product, an authorized representative of the Administrator shall, if the detention is to continue, give written notification to the owner of the biological product detained by furnishing a written statement which shall include the identity and quantity of the product detained, the location where detained, specific description of the alleged noncompliance including reference to the provisions in the Act or the regulations which have resulted in the detention, and the identity of the authorized representative of the Administrator; or, if such owner cannot be ascertained and notified within such period of time, furnish such notice to the agent representing such owner, or the carrier or other person having custody of the biological product detained. The notification, with a copy of the preliminary notice of detention shall be served by either delivering the notification to the owner or to the agent or to such other person, or by certifying and mailing the notification, addressed to such owner, agent, or other person, at the last known residence or principal office or place of business.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

### § 118.3 Movement of detained biological products; Termination of detention.

Except as provided in paragraphs (a) and (b) of this section, no biological product detained in accordance with the provisions in this part shall be moved by any person from the place at which such product is located when it is detained.

(a) A detained biological product may be moved from the place at which it is located when so detained for the purpose of providing proper storage conditions if such movement has been approved by an authorized representative of the Administrator; *Provided*, That, the biological product so moved shall be detained by an authorized representative of the Administrator after such movement.

(b) A detained biological product may be moved from the place at which it is detained on written notification by an authorized representative of the

### 9 CFR Ch. I (1–1–05 Edition)

Administrator that the detention is terminated; *Provided*, That, the conditions under which the detained biological product may be moved will be specified in the written notification of the termination. The notification of termination shall be served by either personally delivering the notification, or by certifying and mailing the notification addressed to such person at the last known residence or principal office or place of business of the owner, agent, or other person having custody of the biological product.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

### § 118.4 Seizure and condemnation.

Any biological product which is prepared, sold, bartered, exchanged, or shipped in violation of the Act or regulations shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court within the jurisdiction of which the product is found. If the product is condemned, it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct, and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the product shall not be sold contrary to the provisions of the Act or the laws of the jurisdiction in which it is sold; *Provided*, That, upon the execution and delivery of a good and sufficient bond conditioned that the product shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws or jurisdiction in which disposal is made, the court may direct that such product be delivered to the owner thereof subject to such supervision by authorized representatives of the Administrator as is necessary to ensure compliance with the applicable laws. When a decree of condemnation is entered against the product and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the product. The proceedings in such libel cases shall conform, as nearly as may be

practicable, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

## **PART 121—POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND TOXINS**

### **Sec.**

- 121.0 Effective and applicability dates.
- 121.1 Definitions.
- 121.2 Purpose and scope.
- 121.3 List of biological agents and toxins.
- 121.4 Exemptions for overlap agents or toxins.
- 121.5 Exemptions for animal agents and toxins.
- 121.6 Registration; who must register.
- 121.7 Registration; general provisions.
- 121.8 Denial, revocation, or suspension of registration.
- 121.9 Registration; how to register.
- 121.10 Responsibilities of the responsible official.
- 121.11 Restricting access to biological agents and toxins.
- 121.12 Biosafety and security plan.
- 121.13 Training.
- 121.14 Transfer of biological agents and toxins.
- 121.15 Records.
- 121.16 Inspections.
- 121.17 Notification in the event of theft, loss, or release of a biological agent or toxin.
- 121.18 Administrative review.

**AUTHORITY:** Secs. 211–213, Title II, Pub. L. 107–188, 116 Stat. 647 (7 U.S.C. 8401).

**SOURCE:** 67 FR 76931, Dec. 13, 2002, unless otherwise noted.

### **§ 121.0 Effective and applicability dates.**

(a) The regulations in this part are effective on February 11, 2003. On and after that date, any person possessing, using, or transferring any agent or toxin listed in § 121.3 must be in compliance with the provisions of this part. However, so as not to disrupt research or educational projects involving listed agents or toxins that were underway as of the effective date of this part, any person possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time

to reach full compliance with this part. Any provision not specifically cited in paragraphs (a)(1) through (a)(6) of this section will be applicable as of February 11, 2003. In addition, any person who does not possess listed agents or toxins by the effective date of this part, but who wishes to initiate a research or educational project prior to November 12, 2003, must be in compliance with the provisions of this part that are applicable for current possessors at the time of application, as provided in paragraphs (a)(1) through (a)(5) of this section.

(1) During the period from February 11, 2003, to November 12, 2003, biological agents or toxins listed in § 121.3 may only be transferred to an individual or entity that is not registered under this part if:

(i) The individual or entity is registered by CDC for that specific overlap agent or toxin in accordance with 42 CFR part 72; or

(ii) The individual or entity has been issued a permit by the Administrator under part 122 of this subchapter to import or move interstate that specific agent or toxin. If an individual or entity has not been issued a permit under part 122 of this subchapter, the individual or entity may apply for a permit. To receive an agent or toxin, an individual or entity will also be required to submit APHIS Form 2041, in accordance with § 121.14(c). Because USDA permits do not cover intrastate movement, unless registered by CDC under 42 CFR part 72, an individual or entity may not receive a listed agent or toxin that is being moved intrastate until that individual or entity is registered in accordance with this part.

(2) By March 12, 2003, the responsible official must submit the registration application package as required in § 121.9. In addition, the responsible official must submit to the Attorney General the names and identifying information for the responsible official; alternate responsible official, where applicable; entity; and, where applicable, the individual who owns or controls the entity.

(3) By April 11, 2003, the responsible official must submit to the Attorney General the names and identifying information for all individuals whom the